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Assessing The Novel Antitrust Claims In Humira Case

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Drug pricing and patent protection have attracted interest among policymakers in recent months. An issue gaining increased attention has been the use of so-called patent thickets to allegedly delay entry by biosimilar versions of biologic drugs.

The proposed Affordable Prescriptions for Patients Act of 2019 (S.1416), and the Affordable Prescriptions for Patients Through Improvements to Patent Litigation Act of 2019 (H.R. 3991), seek to limit the number of patents that can be asserted against a proposed biosimilar entrant.[1]

The Federal Trade Commission and the U.S. Food and Drug Administration released a joint statement in February announcing greater antitrust scrutiny of patent settlement agreements between biologic and biosimilar manufacturers.[2] Patent thickets were also a frequent discussion topic at the FDA/FTC's follow-up workshop in March.[3]

Policymakers and regulators are not alone in their concern with the extent of competition offered by biosimilars.

In a consolidated class action filed in the U.S. District Court for the Northern District of Illinois — In re: Humira (Adalimumab) Antitrust Litigation — indirect purchasers accuse AbbVie Inc. of anti-competitive conduct to maintain a monopoly over its best-selling biologic drug Humira.[4]

The plaintiffs' claims focus on AbbVie's alleged creation and use of a "seemingly impregnable fortress" of patents to delay entry of biosimilar versions of Humira. In making these claims, the plaintiffs introduce novel antitrust theories that would potentially hold a pharmaceutical company liable for the acquisition and/or enforcement of its patents.

Addressing these issues under antitrust law, as the plaintiffs seek to do, raises important legal and economic questions not implicated by the legislative proposals. Can the sheer number of patents relating to a drug — a so-called patent thicket — be considered an anti-competitive barrier to entry? When, if ever, is the accumulation and enforcement

(actual or potential) of such a patent portfolio anti-competitive?

AbbVie's Humira Patents and Biosimilar Entry

First approved by the FDA in December 2002, Humira (adalimumab) is a biologic drug indicated for the treatment of a range of conditions, including rheumatoid arthritis, Crohn's disease, and psoriasis. It is currently the world's most successful biopharmaceutical product, generating nearly $15 billion in U.S. sales revenue in 2019.[5]

The Biologics Price Competition and Innovation Act of 2009 establishes the approval process for biosimilar versions of biologics such as Humira. This includes a framework for resolving patent infringement allegations against biosimilars meant to accommodate the complexity of those disputes.

The BPCIA calls for an initial round of information sharing between the parties, the so-called patent dance, to generate a list of patents the biosimilar might infringe. This is followed by up to two potentially overlapping rounds of patent litigation.[6] The first round is meant to address the most important patents in dispute as selected by the parties; the second round can address any remaining patents from the list.

According to the pleadings in the antitrust litigation, the original compound patent on Humira expired in December 2016. Several companies sought to enter with biosimilar versions of Humira following that expiration. AbbVie holds other Humira-related patents, however, likely more than 100, most belonging to one of nine or more patent families.[7] Some of these were filed around the time of Humira's approval and expire in 2023 or earlier. Others were filed later and have expiration dates ranging up to 2034. AbbVie allegedly listed most or all of these patents as potentially infringed during the patent dance phase. The parties settled before or during the first litigation round with agreements that permit the biosimilars to launch in the U.S. in 2023.

The Antitrust Litigation

The plaintiffs' complaint states that AbbVie obtained and enforced its Humira-related patents as part of an anti-competitive scheme to delay biosimilar entry beyond the 2016 expiration of Humira's original compound patent. According to the plaintiffs, AbbVie spent years cultivating its patent thicket, knowing most of the patents are "weak," in that they are likely invalid and/or not infringed by biosimilars. AbbVie then asserted these patents against biosimilar applicants, allegedly without regard to the merits.

The "sheer volume" of those patents purportedly deterred biosimilar companies from litigating to conclusion AbbVie's infringement claims by increasing the expected costs, duration and risk of litigation. This allegedly gave AbbVie undue leverage in its settlement negotiations with biosimilar companies, resulting in later entry dates for biosimilars than would have occurred but for the alleged anti-competitive scheme.

The litigation is in the pre-discovery stages, with a motion to dismiss pending before the court. A decision on that motion is expected soon.

Broader Relevance

Even if their applicability is limited to biologics, the plaintiffs' antitrust theories have significant implications. Biologics accounted for seven of the ten top-selling drugs in the U.S. and over 20% of novel FDA approvals in 2019.[8] Biologics tend to involve many distinct, patentable inventions; accordingly,

sizable patent portfolios are the norm.[9] Settlements are also commonplace in biosimilar patent litigation, as is generally true in litigation.[10]

If courts recognize the plaintiffs' theories, allegations of anti-competitive patent thickets on biologics could become routine. The FTC and the FDA are said to be watching this litigation closely.[11] Depending on the outcome of the case, these agencies may start their own enforcement efforts targeting patent thickets.[12] Finally, a broader ruling that patent thickets can constitute monopolization could affect other industries, especially in the high-tech sectors, where companies often accumulate large patent portfolios.

Issues in Assessing Patent Thicket Claims

When does a patent portfolio become a patent thicket that might warrant antitrust scrutiny? Any given patent may be found invalid, noninfringed or otherwise unenforceable, notwithstanding an initial presumption of validity. Yet the patent system has also been viewed as an important mechanism for protecting the returns to research and development by providing a right to exclude would-be imitators, subject to certain limitations.

This being the case, what would mark the accumulation and use of pharmaceutical patent rights as an anti-competitive activity? As one would expect, a large patent portfolio alone is insufficient. In 1950, the U.S. Supreme Court stated that the "mere accumulation of patents, no matter how many, is not in and of itself illegal."[13] Asserting many patents in litigation by itself also falls short. Meritorious claims do not become anti-competitive when there are more of them. However, a potential avenue for a claim of anti-competitive conduct may be that a patent thicket has been acquired or asserted in sham or fraudulent petitions.[14]

How should courts assess antitrust injury in such cases? At the core of the plaintiffs' complaint is the claim that companies can use a large number of "weak" patents to delay competitive entry beyond what the patent system intends. But how should courts determine what the patent system intends? Is it based on what would have happened if courts had decided the patent infringement claims? Can defendants defeat such a claim by showing they had a reasonable likelihood of success in their infringement suits against biosimilar applicants? Depending on the answers to these questions, both the number and quality of patents in a thicket have complicated implications for causation.

If one or more "strong" (i.e., valid and enforceable) patents can defeat causation, then under some circumstances, patent thickets should be less likely to give rise to an anti-competitive effect as they increase in size. Suppose, illustratively, each patent in a portfolio could be assigned an index of "quality" summarizing its degree of validity, infringement, and enforceability in a particular context. Then one could rank the patents in the portfolio by this quality index.

Suppose also that there is some quality threshold lying between these values that separates strong patents from weak patents. Then holding other factors constant, increasing the size of the patent portfolio would tend to result in more patents at all quality levels, including above the threshold. These higher-quality patents may presumably be used to exclude competitors without giving rise to an antitrust claim.

Now, suppose that there exists a patent portfolio universally comprised of weak patents. One might surmise that such a portfolio would be unlikely to block biosimilar entry if evaluated in court. This is not the case.

Consider a hypothetical patent portfolio made up of 10 patents (or families of related patents) that are independent of one another.[15] Let us assume that they are relatively weak, in that each one has only a 25% chance of being found valid, enforceable and infringed. Then the probability of all patents (or patent families) being rejected is only 6%, meaning that the probability a court would rule in the patent holder's favor is 94%.[16]

If each independent patent is very weak, with only a 5% chance of being found valid, enforceable and infringed, then the probability a court would rule in the patent holder's favor is 40%. Even in this case, therefore, there is a significant chance the patent holder would have a valid legal right to block the competitor's entry.

This is not merely an academic exercise. A potential entrant facing litigation from an incumbent with a large patent portfolio will be expected to consider its likelihood of success relative to proposed entry dates under a settlement agreement. According to the Supreme Court's logic in FTC v. Actavis,[17] the lower the probability of a successful patent challenge, the later the agreed-upon entry date. The discussion above shows that a later entry date can be driven by a large patent portfolio comprised of relatively weak (but independent) patents, since the odds of at least one patent remaining viable are high. Is the use of a such a portfolio of probabilistically weak patents in settlement negotiations anti-competitive?

There could be extreme cases; hypothetically, some patents could be illegitimate or egregiously weak. Patents acquired through fraud or sham petitions could fall into this category. Other examples may exist; for example, the plaintiffs state AbbVie should be estopped from relying on any patents filed after Humira's original composition patent (or after Humira's 2002 launch), alleging that those patents could not possibly be valid and infringed by a biosimilar.

Yet if the plaintiffs are correct about relevant patents being extremely weak, that very weakness may lessen or eliminate their potential anti-competitive effects. Anti-competitive harm would be expected to operate via increasing BPCIA litigation costs, duration and risk. Patent infringement claims that are objectively baseless or spurious on their face — as the plaintiffs allege about AbbVie's later-filed patents — would be relatively easy to resolve in patent litigation.

This claim also pushes antitrust beyond its normal boundaries and into the territory of patent law. The U.S. Patent and Trademark Office reviews each patent before issuing it. Courts review these decisions (along with infringement allegations) through patent litigation. That process can be slow and expensive, but biosimilar manufacturers can (and frequently do) use inter partes review to challenge patents quickly and at lower cost. Antitrust litigation may also be slow and expensive; as such, it is not obviously the correct instrument to address concerns that the USPTO grants weak patents, that courts might enforce patents improperly, or that the IPR process is inefficient.

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[1] "S.1416 - Affordable Prescriptions for Patients Act of 2019," Congress.gov,

https://www.congress.gov/bill/116th-congress/senate-bill/1416/text; "H.R.3991 - Affordable Prescriptions for Patients Through Improvements to Patent Litigation Act of 2019," Congress.gov, https://www.congress.gov/bill/116th-congress/house-bill/3991/text.

[2] See "Joint Statement of the Food & Drug Administration and the Federal Trade Commission Regarding a Collaboration to Advance Competition in the Biologic Marketplace" ("FDA/FTC Joint Statement"), FTC.gov, February 3, 2020, https://www.ftc.gov/system/files/documents/public_statements/1565273/v190003fdaftcbiologicsstatement.pdf.

[3] See "FDA/FTC Workshop on a Competitive Marketplace for Biosimilars," FDA.gov, March 9, 2020, https://www.fda.gov/media/136791/download.

[4] Mayor and City Council of Baltimore et al., vs. AbbVie Inc. et al., in the United States District Court for the Northern District of Illinois, Eastern Division, Civil Action No. 19-cv-01873, Consolidated Class Action Complaint and Jury Trial Demand.

[5] "AbbVie Reports Full-Year and Fourth-Quarter 2019 Financial Results," AbbVie Press Release, February 7, 2019, https://news.abbvie.com/news/press-releases/abbvie-reports-full-year-and-fourth-quarter-2019-financial-results.htm.

[6] See 42 U.S.C. § 262(l).

[7] See Jeff Wu & Claire Wan-Chiung Cheng, "Into the Woods: A Biologic Patent Thicket Analysis," 19 Chicago-Kent J. Intell. Prop. 93, 111, 130, Table 5 (2020).

[8] "The top selling prescription drugs by revenue," Pharmaceutical Technology, https://www.pharmaceutical-technology.com/features/top-selling-prescription-drugs/; "Novel Drug Approvals for 2019," FDA, https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2019.

[9] See Wu & Cheng, "Into the Woods," supra note 6, at 108-37.

[10] See Joshua Whitehill and Michael Cottler, "Biosimilar Patent Litigation May Be On the Rise in 2020," Law360, January 14, 2020, https://www.law360.com/articles/1233416 (finding a steep decline in pending biosimilar patent litigations in 2019 "mainly due to a large number of settlements").

[11] See Christopher Cole, "Feds Eye Tougher Oversight of Deals Blocking Biosimilars," Law360, March 10, 2020, https://www.law360.com/articles/1251821/feds-eye-tougher-oversight-of-deals-blocking-biosimilars.

[12] See "FDA/FTC Joint Statement," supra note 3.

[13] Automatic Radio Mfg. Co. v. Hazeltine Research, 339 U.S. 827, 834 (1950).

[14] United Food & Commercial Workers Unions & Employers Midwest Health Benefits Fund et al. v. Novartis Pharmaceuticals Corp. et al., 902 F.3d 1, 8-9 & 13-14 (1st Cir. 2018).

[15] By this we mean the outcome of each patent's or patent family's assessment does not depend on

(or affect) the outcome of others.

[16] The probability of all patents being rejected is 0.7510 = 0.06; the probability of at least one not being rejected is, therefore, 1 - 0.06 = 0.94.

[17] FTC v. Actavis, Inc., 570 U.S. 136 (2013).